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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/646,442

08/22/2003

Theodore R. Kucklick

212/497

9500

7590

05/17/2006

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EXAMINER

MEHTA, BHISMA

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/646,442	KUCKLICK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bhisma Mehta	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/22/03</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, “the plurality of grooves disposed in the distal portion of the cannula, wherein at least one groove is disposed between two particular slots in a row of slots” with the plurality of longitudinally staggered rows of slots must be shown or the feature(s) canceled from the claim(s). Additionally, the longitudinally staggered rows of slots being longitudinally aligned with each other and at least one groove being disposed around the entire circumference of the tube must be shown or the feature(s) canceled from the claim(s). Also, “the plurality of grooves disposed in the distal portion of the cannula, wherein at least one groove is disposed between two particular slots in a row of slots” where the slots in the longitudinally staggered rows are a) longitudinally oriented and b) circumferentially oriented must be shown or the feature(s) canceled from the claim(s). Furthermore, the surgical instrument port having a valve operably connected to the rigid tube and a clamp operably connected to the rigid tube must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "100" has been used to designate both the exploded view of the instrument port in Figure 7 and the cannula in Figure 11. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the

description: b in Figure 2. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. The disclosure is objected to because of the following informalities:
  - a. In lines 20-22 of page1, it appears that there is some missing text as it is unclear what is provided to deliver fluid to the cannula.
  - b. In lines 7 and 9 of page 8, it appears that "valve 46" should be ""valve 44" as reference character 44 has previously been used to describe the valve and reference character 46 is used to describe the flexible segment.
  - c. In line 3 of page 11, a "." is incorrectly used at the beginning of the paragraph.

Appropriate correction is required.

***Claim Objections***

5. Claims 1-22 are objected to because of the following informalities:
- a. Claim 1 recites the limitations "the distal portion of the tube" in line 5 of the claim and "the distal end of the tube" in line 11 of the claim. There is insufficient antecedent basis for these limitations in the claim.
  - b. Claims 2, 7, and 12 recite the limitation "the proximal portion of the tube" in lines 2-3 of the claims. There is insufficient antecedent basis for this limitation in the claims.
  - c. Claim 5 recites the limitation "the distal portion of the cannula" in lines 3-4 of the claim. There is insufficient antecedent basis for this limitation in the claim.
  - d. Claims 10 and 13 recite the limitation "the distal end of the tube" in line 3 of claim 10 and in line 4 of claim 13. There is insufficient antecedent basis for this limitation in the claims.
  - e. Claim 11 recites the limitations "the distal portion of the rigid tube" in line 14 of the claim and "the distal end of the tube" in line 28 of the claim. There is insufficient antecedent basis for these limitations in the claim. The recitation of the limitations "the distal portion of the tube" in line 22, "the tube" in line 24, "the lumen of the tube" in line 25-26, "said tube" in line 27, and "the distal end of the tube" in line 28 make it unclear as to which tube (the rigid or flexible) and which lumen (the lumen of the rigid tube or of the flexible tube) applicant is referring to.
  - f. In claim 17, it is unclear what is meant by "a second tube" because a first tube has not been established.

g. Claim 20 recites the limitations "the distal portion of the rigid tube" in lines 17-18 of the claim. There is insufficient antecedent basis for this limitation in the claim. The recitation of the limitations "the distal portion of the tube" in lines 25-26, "the tube" in line 28, "the lumen of the tube" in line 29-30, "said tube" in line 31, and "the distal end of the tube" in line 32 make it unclear as to which tube (the rigid or flexible) and which lumen (the lumen of the rigid tube or of the flexible tube) applicant is referring to.

h. Claim 22 recites the limitations "the distal portion of the rigid tube" in lines 17-18 of the claim. There is insufficient antecedent basis for this limitation in the claim. The recitation of the limitations "the distal portion of the tube" in line 25, "the tube" in line 27, "the lumen of the tube" in line 28-29, "said tube" in line 30, and "the distal end of the tube" in line 31 make it unclear as to which tube (the rigid or flexible) and which lumen (the lumen of the rigid tube or of the flexible tube) applicant is referring to. In line 15 of the claim, it appears there is text missing between the words "substantial" and "of".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 22 recites the limitation "the lumen in the port" in lines 34-35. There is insufficient antecedent basis for this limitation in the claim.



***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 11, 13, 16, 18, and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Samson et al (U.S. 5,782,811). In Figures 1 and 7, Samson et al show a rigid tube (106), a valve (110), and a cannula having a flexible tube (102) where the distal portion of the tube has a plurality of longitudinally staggered rows of slots (269) disposed along a longitudinal line of the tube and where the slots are in fluid communication with the lumen of the tube. The slots are longitudinally oriented. In lines 47-60 of column 6, Samson et al disclose that tubes can be made where the diameter of the distal section can become smaller thus leading to a smaller thickness at the distal end of the tube. The valve (110) includes a fluid port as seen in Figure 1. In Figure 13, Samson et al show a surgical instrument (532) which has been inserted through the cannula and which has a curved distal portion. In lines 35-46, Samson et al disclose methods involving delivering diagnostic or therapeutic agents to surgical sites

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:



(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 3, 5, 6, 8, 10, 11, 13, 15-18, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce (U.S. 5,800,409) in view of Clement et al (U.S. 5,203,769).

In Figures 2 and 5, Bruce show a rigid tube (26) having a lumen (39), a valve (44), and a cannula attached to the distal portion of the rigid tube and having a flexible tube (14) where the distal portion of the tube has a row of slots (34) disposed along a longitudinal line of the tube and where the slots are in fluid communication with the lumen (38) of the tube. As to claim 5, in Figure 2, a plurality of circumferential grooves are shown between each of the slots (34) and each groove is disposed around the entire circumference of the tube. As to claims 10 and 13, in lines 31-38 of column 3, Bruce teaches that the tube (14) is tapered such that the thickness of the tube tapers along the direction of the distal end of the tube thus allowing the tube to become increasingly flexible in that direction. As to claim 15, the cannula is considered to be removably attached to the rigid tube as Bruce states that the preferred embodiment would be a single piece instrument and thus another embodiment would be one in which the cannula is removable. In lines 1-10, Bruce discloses that other materials having the requisite flexibility properties may also be used to manufacture the cannula. This would be the embodiment where the cannula would be removably attached to the rigid tube, as the material used for the cannula would not necessarily be the same material that could be used for the rigid housing. As to claim 16, in Figure 2, a fluid port

(42) is in fluid communication with the lumen of the rigid tube. As to claims 20 and 21, in Figure 5, a surgical instrument (54) with a curved distal portion is shown inserted into a surgical instrument port and extending through the lumen of the rigid tube and the lumen of the cannula. Bruce also teaches using the rigid tube, valve, and cannula to perform an arthroscopic surgery procedure as claimed in claim 22.

As to claims 1, 3, 6, 8, 11, and 18, Bruce discloses the surgical instrument port having a rigid tube (26), a valve (44), a cannula (14), and a surgical instrument (54) and the method of performing the arthroscopic surgery procedure substantially as claimed. However, Bruce does not disclose the cannula having a plurality of longitudinally staggered rows of slots. Clement et al disclose a surgical instrument port system as shown in Figure 11 having a rigid tube (12), a valve (50), and a flexible cannula (200) where the distal portion (202) of the cannula has a plurality of longitudinally staggered rows of slots (204) which are longitudinally aligned with each other. Clement et al also teach that the slots may be longitudinally oriented as shown in Figure 27. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the row of slots on the cannula of Bruce with a plurality of longitudinally staggered rows of slots which are longitudinally aligned with each other as taught by Clement et al as both Bruce and Clement et al teach using the slots on the cannula for introducing and removing fluid from a surgical site and Clement et al teach that it is advantageous to use a plurality of longitudinally staggered rows of slots which are longitudinally aligned with each other on the cannula. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute

the slots of Bruce with the longitudinally oriented slots as taught by Clement et al as Clement et al teach that fluid can be delivered to a surgical site through a variety of slot configurations, including longitudinally oriented slots.

As to claim 17, even though Bruce discloses using a valve for controlling the flow of fluid to and from a surgical site, Bruce does not teach using a clamp which is operably connected to the rigid tube and which can be used to restrict the flow of fluid through the instrument port. Clement et al teach using a clamp (60) which is operably connected to the rigid tube (12) and which can be used to restrict the flow of fluid through the instrument port. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the instrument port of Bruce with a clamp as taught by Clement et al as a means to control the flow of fluid to and from a surgical site.

12. Claims 2, 7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce in view of Clement et al as applied to claims 1 and 11 above, and further in view of Theeuwes et al (U.S. 6,638,263). Bruce and Clement et al disclose the invention substantially as claimed. However, Bruce and Clement et al are silent on the proximal portion of the tube having a plurality of circumferential ridges. In lines 13-54 of column 14, Theeuwes et al teach that a catheter may be tapered at the distal end relative to the proximal end to allow the catheter to be more flexible and more easily inserted into a surgical site and also teach that the outer surface of the catheter may have a plurality of circumferential ridges which would be desirable for specific applications. It would have been obvious to one having ordinary skill in the art at the

time the invention was made to provide the proximal portion of the cannula of Bruce with a plurality of circumferential ridges as taught by Theeuwes et al as both Bruce and Theeuwes et al teach that it is desirable to have a more flexible distal portion on a tube that is to be inserted into a body and Theeuwes et al teach in lines 13-26 that it is well known that circumferential ridges can be placed on the outer surface of a tube as such a variation may be desirable for the specific application for which the tube will be used.

13. Claims 4, 9, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce in view of Clement et al as applied to claims 1 and 11 above, and further in view of Ott (U.S. 6,733,479). Bruce and Clement et al disclose the invention substantially as claimed. Even though Bruce discloses a cannula having a plurality of slots, Bruce is silent on the slots being circumferentially oriented. Ott discloses a tube having circumferentially oriented slots as shown in Figures 5 and 7. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the slots of Bruce with the circumferentially oriented slots as taught by Ott as Ott teaches in lines 26-47 of column 7 that fluid can be delivered to a surgical site through a variety of slot configurations including circumferentially oriented slots.

14. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce in view of Clement et al as applied to claim 11 above, and further in view of Davis et al (U.S. 6,159,182). Bruce and Clement et al disclose the invention substantially as claimed. Bruce discloses using a valve for controlling the flow of fluid to and from a surgical site and for allowing a surgical instrument to be inserted through the cannula. However, Bruce does not teach the valve being a duckbill valve. In lines 40-59 of

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column 1, Davis et al teach using a duckbill valve which is operably connected with a cannula and which can be used to allow a surgical instrument to be inserted through the cannula without allowing flow of fluid through the valve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the valve of Bruce with the duckbill valve as taught by Davis et al as Davis et al teach that it is well known to use duckbill valves to control fluid flow when a surgical instrument is inserted into a cannula.

### ***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kulik et al (U.S. 4,643,712), McIntire (U.S. 6,170,137), Breznock (U.S. 6,638,253), and Savage et al (U.S. 6,669,679) disclose cannulas having a plurality of longitudinally staggered slots.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*BM*  
BM

KEVIN SIRMONS  
PRIMARY EXAMINER

*Kevin C. Sirmons*  
5/15/06